

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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SUISSE

## PCT

WRITTEN OPINION  
(PCT Rule 66)

Applicant's or agent's file reference ES032PCT		Date of mailing (day/month/year)	28.06.2004
REPLY DUE		within 1 month(s) from the above date of mailing	
International application No. PCT/CH 02/00349	International filing date (day/month/year) 26.06.2002	Priority date (day/month/year) 26.06.2002	
International Patent Classification (IPC) or both national classification and IPC A61B5/042			
Applicant ENDOSENSE S.A.R.L. et al.			

- This written opinion is the first drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☐ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.
 


**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.8.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 26.10.2004

Name and mailing address of the international preliminary examining authority:

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**WRITTEN OPINION**International application No. **PCT/CH 02/00349****I. Basis of the opinion**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

4-7 as originally filed  
1, 2, 3, 3a filed with telefax on 09.06.2004

**Claims, Numbers**

1-6 filed with telefax on 09.06.2004

**Drawings, Sheets**

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire International application,

☒ claims Nos. 1-6

because:

☒ the said international application, or the said claims Nos. 1-4 relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 5,6 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

**Section III:**

1. For the assessment of the present claims 1-4 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The IPEA therefore is not required to carry out an examination on these claims (Cf. Rule 67.1(iv) PCT).

The patentability may be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

The above claims pertain to a method of cardiac catheterisation which is considered surgical in its nature as it implies the insertion of a catheter into the human or animal body, be it by way of incision or by using natural body orifices. Thereby the entire method is rendered surgical. Methods of surgery might not be regarded as an invention susceptible of industrial application.

2. Claim 5 specifies the feature according to which the catheter is provided with at least one sensor adapted to detect any inversion of the catheter tip.

According to the passages as cited in the applicant's letter of reply in support of the amended claims, neither original claims 1,2,4 nor page 2, lines 6-18 provide a basis for such a sensor. Rather, a sensor is originally disclosed that delivers signals associated with cardiac activity.

If claim 5 were to be presented amended to include the features of current claim 6, such a new claim 5 is considered to meet the requirements of Art.33 PCT as no prior art as cited in the ISR discloses, nor renders obvious, such a combination of sensors in the present context.

3. Formal items to be addressed are:

- 3.1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

- 3.2. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see document US-A-6 370 412) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in

**WRITTEN OPINION  
SEPARATE SHEET**

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a characterising part (Rule 6.3(b)(ii) PCT).